



October 2, 2008

Report SANITIZED of Confidential Business Information

DELIVERY BY FEDERAL EXPRESS
CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RECEIVED
CPT/CBIC
2008 OCT -9 AM 8:03

SUBJECT: **TSCA 8(e) SUBMISSION**

Dear Sir or Madam,

 (" ") is submitting certain data which we believe to be reportable under TSCA 8(e).
The information concerns (), an experimental pyrethroid insecticide. is
identified by IUPAC as:



The CAS number assigned for this compound is

 has imported for R&D on behalf of
(" ").

The following reports concerning have been submitted to your agency: Two acute oral
toxicity studies with rats (November 15, 2007:); a preliminary
developmental toxicology study with rats (January 7, 2008:); a micronucleus
study with rats (February 19, 2008:); and an acute inhalation study with rats
(July 10, 2008:).

recently learned of new toxicological effects in a subacute oral toxicity study performed with dogs. An outline of the study follows:

2Week Oral (Capsule) Toxicity Study of in Dogs

Study conducted by: (Study No.)
Animals: Beagle dogs, male & female, 6 months old; 1 animals/sex/dose at initiation of study
Dose: 0 (control), and 50, 500, and 1000 mg/kg/day
Administration: oral (via capsule), one per day for 2 weeks
Body weight: females:5.6 -8.0 Kg; males: 8.5-9.9 Kg (at initiation of the study)
Observation: The animals were monitored for clinical signs before administration of the test substance and at approximately 1, 3 & 6 hours after application of treatment, then once daily through the completion of the 14 day study

Examinations conducted: clinical signs, body weights, food consumption, ophthalmoscopic examinations, hematology, clinical biochemistry, urinalysis, pathology, organ weights, and histopathology

The following adverse health effects were noted during the course of this study which believes to be reportable under TSCA 8(e): Clinical signs of tremor and salivation in animals receiving the 1000 mg/kg/day dose and salivation and tachypnea in animals receiving doses of 500 mg/kg. The NOAEL was determined to be 50 mg/kg/day which is below the 200 mg/kg/day criteria for EPA. See summary below for further details.

One male dog was sacrificed after administration of a single 1000 mg/kg dose of the test substance due to persistent signs of tremor and tachypnea.

The two dogs of the 500 mg/kg/day dose group and the female in the 1000 mg/kg/day dose group had decreased food consumption and body weight loss, as well as watery feces and vomiting of mucus, food or the test substance. Somnolence was observed in females of the 500 mg/kg/day and 1000 mg/kg/day dose groups. We believe that this is attributable to poor physical conditions of these dogs.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts

to commercialize this compound. Please refer to the attached letter of
Edward Gross regarding substantiation of CBI claims.

to Mr.

If there are any questions on this submission please feel free to contact me at ().

Yours sincerely,

Encl.

cc:

SANITIZED OF CONFIDENTIAL BUSINESS INFORMATION

November 13, 2007

MR#314593

Document Processing Center
EPA East (Mail Code 7407M)
Attention: Mr. Edward Gross, TSCA Section 8(e) Coordinator
U. S. Environmental Protection Agency
1201 Constitution Avenue, NW, Suite 6428
Washington, DC 20460-0001

Subject: TSCA 8(e) Submission: Substantiation of CBI Claims in enclosed report

Dear Mr. Gross:

This letter is to substantiate the claim made for the Confidential Business Information ("CBI") concerning the experimental pesticide identified as _____ in our letter of November 14, 2007 which contains findings of a toxicological study we believe to be reportable under TSCA 8(e). We are providing this substantiation on behalf of our client, ("_____"), the developer of this pesticide. We (_____. ["_____"]) are responding to each item listed on the Substantiation Attachment (entitled *Support Information for confidentiality Claims*) as follows:

1. Identity of CBI Claimant

We are asserting CBI claims on behalf of:

Company Sanitized

2. Duration and Basis for Need of CBI Claim

At this time, cannot predict if or when it will apply to register this chemical. does, however, need to assert its CBI claim until such time as EPA may publish a public notice in the Federal Register announcing that has made application to register as a new pesticide active ingredient. Such application would prompt a notice in the Federal Register identifying the active ingredient. Until EPA publishes such a notice, the information claimed as CBI reflects 's confidential business plan for the commercial development of this chemical. The disclosure of this information would harm 's efforts to commercialize this chemical.

3. Previous Submissions

There have been no previous submission regarding adverse effects of .

4. Use and Storage of CBI at

All CBI information is kept in a locked building accessible only to staff. This building is protected by an ADT alarm system. All staff members have signed agreements prohibiting them from disclosing confidential information.

5. Access to CBI by Persons Not Employed by

No other persons have access to CBI contained at .

6. Appearance of CBI in Advertising, MSDS, or Publications

- a) Information claimed as CBI does not appear in any advertising or promotional material.
- b) Information claimed as CBI may appear in a Material Safety Data Sheet; however, this information is only available to parties bound by secrecy agreements made between them and .
- c) Information claimed as CBI does not appear in any professional or trade publications.
- d) Information claimed as CBI does not appear in any other media source or in publications made available to the public or to 's competitors.

7. Confidentiality Determinations by EPA, Other Agencies, or the Courts

No confidentiality determinations have been made on information claimed as CBI by EPA, other Agencies, or by the Courts.

8. Substantial Harmful Effects of Disclosure of CBI

As noted above under item 2, _____ needs to assert its CBI claim until EPA publishes a Federal Register notice that an application has been made to register _____ as a new pesticide. It is very important to _____ to preserve confidentiality regarding _____ for competitive business reasons.

Disclosure of information claimed CBI could erode the valuable head start that _____ currently enjoys in development of _____ prior to its application to EPA for registration. We are, therefore, requesting that the identities of and relationships between _____, _____ and _____ be maintained as CBI. _____ has a US patent (see item 9 below). In the pesticide business many compounds prove unsuitable for commercialization, and _____'s compounds are no exception to this rule. Indeed, _____ rigorously screens those compounds which are selected for potential commercialization, thus further winnowing the number of successful candidates. The knowledge that _____ is actively developing this particular chemical would be valuable to its competitors who could then modify their product development and market strategies to counter the introduction of _____ into the market place.

Knowledgeable competitors would conclude that _____ is involved in the development of this pesticide upon learning that _____ has filed a TSCA 8(e) submission for _____; especially as _____ and I, as its _____, have handled registration matters for _____ for many years. I am listed as an agent for _____ under the title of _____, and have often dealt with _____'s competitors in this capacity; therefore, my affiliation is well known.

9. Patent Status

a) The US Patent Office has assigned patent number _____ to this substance.

10. Commercial Availability

a) _____ is not available in the market place nor is it used or sold for commercial purposes.

11. Reverse Engineering

Competitors could be encouraged to seek ways to synthesize or produce derivatives of this if they knew that _____ is actively developing _____ as a _____ insecticide compound.

12. What Disclosure of Information Would Reveal

a) No confidential manufacturing processes would be revealed.

b) The composition of _____ is indicated in its chemical name; thus, information on the synthesis of _____ would be revealed.

- c) The planned entry of _____ into the pesticide market would be revealed. Disclosure would reveal _____'s plans to enter into this market with a class of chemical represented by _____.

13. CAS Number

The CAS Number for _____ is _____.

14. Information Subject to FIFRA Regulation or Reporting

The CBI claimed on _____ is not subject to FIFRA regulation or reporting as no applications have been submitted for experimental use permits or for registration.

We look forward to hearing the Agency's determination regarding the CBI claims discussed in this letter. Should there be any questions or the need for further information, please do not hesitate to contact me at _____ by telephone; _____ by telefax; or via e-mail at _____.

Sincerely yours,

cc: